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10/059,521	01/29/2002	Ivan N. Rich	R103 1030.1	5794

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FROMMER LAWRENCE & HAUG
THOMAS J. KOWALSKI
745 FIFTH AVENUE
NEW YORK, NY 10151

EXAMINER	
GABEL, GAILENE	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/059,521	RICH, IVAN N.	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-56* is/are pending in the application.

4a) Of the above claim(s) *29,30,32-41 and 45-56* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28,31 and 42-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-56* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. Applicant's amendment and response, filed May 6, 2005 is acknowledged and has been entered. Claims 1, 20, and 42-44 have been amended. Claims 29, 30, 32-41, and 45-56 remain withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being claims drawn to a non-elected invention. Currently, claims 1-56 are pending. Claims 1-28, 31, and 42-44 are under examination.

Oath/Declaration

2. The Office acknowledges Applicant's submission of a corrected oath or declaration.

Withdrawn Rejections

3. All rejections not reiterated herein, have been withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 42 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 42 is vague and indefinite in reciting, "whereby the population is indicated by a positive proliferative status" because it is unclear what Applicant intends to encompass by term "positive" as used in the claim. Does Applicant intend that there is a presence of proliferation in the cells as indicated by the amount of ATP? Claim 42 also appears redundant and confusing in reciting, "having a positive proliferative status having a proliferative status."

In claim 44, line 6, "status of the of target cell population" should be --status of the target cell population.--

Claim 44 is indefinite in having improper antecedent basis in reciting, "a target population" in the last two lines of the amended claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-28, 31, and 42-44 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Crouch et al. (Journal of Immunological Methods, 160: 81-88 (1993)) in view of Bell et al. (US 2002/0120098 A1) for reasons of record and as follows.

Crouch et al. disclose an assay method for determining the proliferative status, i.e. cell proliferation, of a population of primitive hematopoietic cells. The hematopoietic cells are granulocyte-macrophage colony-forming cells (GM-CFC) and granulocyte colony-forming cells (G-CFC), i.e. TF-1 and NFS-60 cells, isolated from human peripheral blood, and are detected for cytokine dependent proliferation by stimulation of granulocyte-macrophage colony stimulating factor (GM-CSF) and granulocyte colony stimulating factor (G-CSF) (see Abstract). Initially, the hematopoietic cell lines from peripheral blood are cultured and maintained in a cell growth culture medium containing 0% to 30% (12.5%) fetal bovine serum (fetal calf serum). Crouch et al. then isolate mononuclear cells (MNCs) from peripheral blood, i.e. containing hemoglobin, in order to render the MNC sample substantially free of hemoglobin. Crouch et al. isolate the MNCs by Ficoll-Hypaque density gradient centrifugation. For ATP bioluminescence assay, Crouch et al. specifically contacts the isolated MNCs with luciferin-luciferase monitoring reagent which generates bioluminescence in the presence of adenosine triphosphate or ATP (see page 81, column 2 and page 82, columns 1 and 2). The amount of luminescence generated by the reagent indicates the amount of ATP in the MNC cell population, wherein the amount of ATP indicates the proliferative status of the hematopoietic cells.

Crouch et al. differ from the instant invention in failing to disclose that the cell growth culture medium includes methyl cellulose having a concentration of about 0.4% to 0.7% methyl cellulose and maintained in an atmosphere having between about 3.5% to 7.5% oxygen. Crouch et al. further differ from the instant invention in failing to disclose generating a hematopoietic population enriched in progenitor cells and stem cells from animal tissue such as bone marrow, fetal liver, and spleen, isolated from cow, sheep, pig, horse, goat, dog, cat, and primates, and determining their suitability for transplantation. Crouch et al. also does not teach isolating and identifying specific subpopulations of primitive hematopoietic cells using cell surface markers. Lastly, Crouch et al. does not teach contacting the primitive hematopoietic cells with a test compound and determining its ability to modulate proliferation of the cells.

Bell et al. disclose compositions and methods comprising heme-containing components for use in inducing and/or enhancing stimulation of hematopoiesis (erythropoiesis), in order to hence, stimulate erythroid progenitor proliferation in a cell culture system. Hematopoiesis involves the proliferation of hematopoietic stem cells and hematopoietic progenitor cells and the stimulation is specific for hematopoietic colony-forming cell erythroid macrophage, megakaryocyte stem cells (CFC-GEMM) (see page 4, column 1, [0026], page 7, column 2, [0071], and page 9, column 2, [0085]). According to Bell et al., the burst forming unit-erythroid (BFU-E) represents the most primitive hematopoietic or erythroid progenitor and forms large multi-clustered hemoglobinized colonies (see page 1, column 1, [0004]). In practice, Bell et al. teach culturing the primitive hematopoietic cells in a cell growth medium comprising 30% fetal

bovine serum, about 0.4% to about 0.7% (0.8%) methyl cellulose which increases viscosity in culture media, and in an atmosphere having between about 3.5% to 7.5% (5%) oxygen. Bell et al. also teach contacting the sample with cytokine such as GM-CSF and Flt3 Ligand to generate a cell population substantially enriched in CFC-GEMM stem cells for use in cell proliferation assay (see page 7, column 2, [0071], page 9, column 2, [0084-0092], and Examples 1 and 2). According to Bell et al., erythroid progenitor colony formation is enhanced at lower, more physiological oxygen tensions, such as 5% oxygen (see page 11, column 1, [0098-0101]. These enriched hematopoietic stem cells or progenitor cells are obtained from bone marrow, cord blood, or peripheral blood, and if determined to have adequate proliferative status, can be transplanted into a recipient patient (see page 4, column 2, [0030] and page 7, column 2, [0078]). Hematopoietic stem cells or progenitor cells can also be obtained and enriched from animal tissue such as bone marrow, cord blood, fetal liver, or spleen, of dog, cow, horse, cat, pig, sheep, goat, chicken, primate, or human (see page 8, column 2, [0076-0078]). Subpopulations of primitive hematopoietic cells are characterized by the presence of specific hematopoietic progenitor cell surface markers such as CD34 and glycophorin A (see page 12, column 1, [0105]). These cell subpopulations can be selectively isolated and purified from other cells (cord blood) and other [heme-containing] sample components by binding the cells with antibodies specific for their cell surface markers such as anti-CD34 and anti-glycophorin A or by magnetic bead separation, i.e. STEMSEP^{TM} system, and other separation systems, i.e. CEPRATE LC system, and selectively determining their identity by flow cytometry or flow activated cell

sorting (see page 17, column 1, [0144 and 0145] and Example 9). Bell et al. further teach contacting primitive hematopoietic cells having a target cell population with a test a compound (Ganciclovir) and determining its ability to modulate, i.e. inhibit, proliferation or differentiation of the target cell population. Result of the testing is compared with negative control (see Example 11).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to substitute the culture growth media composition as taught by Bell having 30% fetal bovine serum, 0.8% methyl cellulose, and in an atmosphere having between about 5% oxygen, for the culture system as taught by Crouch for maintaining cells suitable for ATP bioluminescence assay, because Bell specifically taught that hematopoietic progenitor cells or stem cells favor survival and growth in a medium having such composition for use in any proliferation assays. One of ordinary skill in the art at the time of the instant invention would have been motivated to incorporate the culture system as taught by Bell which stimulates proliferation of hematopoietic cells, for subsequent use as MNC sample for testing proliferation status using the ATP bioluminescence assay as taught by Crouch, because methyl cellulose is conventionally known to advantageously increase viscosity of proliferating cells in culture media and Bell specifically taught that erythroid progenitor colony formation is even further enhanced at lower, more physiological oxygen tensions, i.e. 5% oxygen; hence, increasing the concentration of hematopoietic progenitor cells for use in assays that measure proliferation of cell populations, including the ATP bioluminescence assay taught by Crouch.

New Grounds of Rejection

New Matter

6. Claims 1-28, 31, and 42-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

In this case, the specification does not appear to provide literal or adequate descriptive support for the recitation of "a cell population comprising primitive hematopoietic cells substantially free of hemoglobin". Applicant points to Example 1 and Example 2 of the disclosure wherein mononuclear cells (MNC) are prepared from human peripheral blood, bone marrow, or umbilical cord, by isolation of the MNC using density gradient centrifugation on Ficoll-Paque Plus. Example 1 provides that one [isolated] MNC sample at a final concentration of 2×10^6 cells/ml originated, and was prepared from peripheral blood. Other [isolated] MNC samples at final concentrations of $0.5\text{-}1 \times 10^6$ and $0.5\text{-}1 \times 10^5$ cells/ml originated, and were prepared from bone marrow and umbilical cord, respectively. It was these isolated or enriched samples of MNCs that were dispensed into 96-well plates which were maintained in culture media for use in ATP luciferase assay. Accordingly, density gradient centrifugation on Ficoll-Paque Plus appears to be performed in order to hence, render the original cellular samples "substantially free of hemoglobin", by virtue of removal of the peripheral red blood cells

containing therein hemoglobin, or any other heme-containing components from the original samples; this at best, is a method step that Applicant has support for in the instant specification; but such teaching fails to provide literal support or adequate descriptive support for the recitation of "a cell population comprising primitive hematopoietic cells substantially free of hemoglobin" in claim 1. Additionally, none of the originally filed claims recited the limitation in question. Recitation of claim limitations lacking literal or adequate descriptive support in the specification or originally filed claims constitutes new matter.

The recitation of "incubating a cell population comprising primitive hematopoietic cells substantially free of hemoglobin" also provides a recitation of a negative limitation excluding hemoglobin from primitive hematopoietic cell sample for use in the claimed method, but the specification only exemplifies a method on how to render a sample, i.e. peripheral blood, substantially free of hemoglobin. The specification does not provide teaching or disclosure for the recitation of the negative limitation in the claims excluding hemoglobin from the sample. Specific guidance in rendering a sample substantially free of hemoglobin is taught, but the recitation of the negative limitation excluding hemoglobin is not supported or disclosed in the instant specification. The limitation in question does not flow from the specification and is therefore considered to encompass new matter. See In re ANDERSON, 176 USPQ 331 (CCPA 1973).

Response to Arguments

7. Applicant's arguments filed May 8, 2005 have been fully considered but they are not persuasive.

A) Applicant argues that the combination of Crouch et al. and Bell et al. does not teach or render obvious the claimed invention because neither of the references provide any motivation to have suggested the teaching, as combined. Applicant specifically contends that Bell et al. teach use of hemoglobin in enhancing proliferation of cells in a culture system; hence, it is not combinable with the luciferase-based ATP system of Crouch et al. since inclusion of hemoglobin molecules interferes with luciferase-based ATP assay systems as it impairs the detection of luminescence due to absorption of light by the heme moiety. Applicant further argues that nowhere in Bell et al. teach the method of the present invention for rapidly determining the proliferative status of any hematopoietic cell-types.

In response to Applicant's argument against Bell et al. individually, wherein the reference does not teach or suggest the method of the present invention which rapidly determines the proliferative status of any hematopoietic cell types, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, the rejection is based on the combination of Crouch as primary reference and Bell as a secondary reference. Crouch obtains hematopoietic cells that are GM-CFCG-CFC, i.e. TF-1 and NFS-60 cells (MNCs), from peripheral blood that has been cultured and maintained in a cell growth culture medium containing 0% to 30% (12.5%) fetal bovine

serum. Crouch then isolates MNCs from the peripheral blood, i.e. containing hemoglobin, in order to render the MNC sample substantially free of hemoglobin using Ficoll-Hypaque density gradient centrifugation. Crouch specifically contacts the isolated MNCs with luciferin-luciferase monitoring reagent which generates bioluminescence in the presence of ATP to perform ATP bioluminescence assay that determines the proliferative status of the hematopoietic progenitor cells. Bell is incorporated herein, only for the disclosure of culture systems which are capable of inducing and/or enhancing stimulation of erythropoiesis, in order to hence, stimulate erythroid progenitor proliferation using heme-containing components. The culture system comprises 30% FBS, about 0.4% to about 0.7% methyl cellulose in an atmosphere having between about 3.5% to 7.5% oxygen. Bell provides that erythroid progenitor colony formation is enhanced at lower, more physiological oxygen tensions, i.e. 5% oxygen. Bell selectively isolates and purifies the erythroid progenitor cells from cord blood, i.e. hemoglobin containing, by binding the cells with antibodies specific for their cell surface markers by magnetic bead separation, i.e. STEMSEP^{TM} system, CEPRATE LC system, prior to further analysis of the cells. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to substitute the culture growth media composition as taught by Bell for that taught by Crouch for maintaining cells suitable for ATP bioluminescence assay because Bell specifically taught that hematopoietic progenitor cells or stem cells favor survival and growth in a medium having such composition for use in any proliferation assays. One of ordinary skill in the art at the time of the instant invention would have been motivated to incorporate the

culture system of Bell which stimulates proliferation of hematopoietic cells, for subsequent use as MNC sample for testing proliferation status using the ATP bioluminescence assay as taught by Crouch, because use of methyl cellulose is conventionally known to advantageously increase viscosity of proliferating cells in culture media and Bell specifically taught that 5% oxygen increases the concentration of hematopoietic progenitor cells for use in assays that measure proliferation of cell populations, including the ATP bioluminescence assay taught by Crouch.

In response to Applicant's argument that the references cited are not combinable because of the use of hemoglobin by Bell in his culture system which is incompatible with luciferase-based ATP detection systems due to interference from absorption of light by the heme moiety in luminescence systems, it is noted that methods taught by Bell incorporate hemoglobin in the culturing systems only to promote growth of erythropoietic cells and stimulation of erythropoietic cell proliferation, and analysis performed thereafter requires isolation of the erythropoietic cells using magnetic cell separation. It is also noted that in the culture systems taught by Crouch, the hematopoietic progenitor cells are isolated or purified from other cells using density gradient centrifugation to remove any other components including those which would have contained hemoglobin therein, such as peripheral blood, before subjecting the cells to luciferase-based ATP bioluminescence assay. Accordingly, Applicant's contention that there is inclusion of hemoglobin in the teaching of Bell which renders it non-combinable with the luciferase-based ATP luminescence assay of Crouch because of the impairing effect of the heme moiety in luminescence systems, is misguided

because both systems individually and selectively require removal of contaminating components, such as heme moieties, prior to subjecting the cells to analysis. Additionally, the components set forth in the combined references are consonant with the elements relied upon for support in the instant disclosure. Specifically, Applicant's support for the recitation of "a cell population comprising primitive hematopoietic cells substantially free of hemoglobin" in Example 1 provides use of Ficoll-Paque Plus to isolate MNCs from peripheral blood prior to proliferation status assay using luciferase based ATP bioluminescence assay. Crouch et al. at page 82, column 2 of the reference also use Ficoll-Hypaque density gradient centrifugation to isolate MNCs from peripheral blood prior to proliferation status assay using luciferase based ATP bioluminescence assay. For at least these reasons, the rejection is being maintained.

Response to Declaration of Dr. Ivan Rich Under 35 CFR 1.132

8. Applicant's statements in the declaration filed May 8, 2005 have been fully considered but they are not persuasive.

A) Dr. Rich performed experiments to show that if hemoglobin is present in luciferase-based ATP bioluminescence assays, there is significant suppression of the luminescence generated by ATP luciferase, thereby rendering the assays unable to correlate luminescence values to the proliferative status of the primitive hematopoietic cell populations. Applicant specifically states that Bell et al. teach use of hemoglobin in enhancing proliferation of cells in a culture system; hence, it is not combinable with the luciferase-based ATP system of Crouch et al. since inclusion of hemoglobin molecules

causes significant suppression of the luminescence generated by ATP luciferase in ATP bioluminescence assays.

In response to Applicant's argument that the references cited are not combinable because of the use of hemoglobin by Bell in his culture system which is incompatible with luciferase-based ATP detection systems due to interference from absorption of light by the heme moiety in luminescence systems, it is noted that methods taught by Bell incorporate hemoglobin in the culturing systems only to promote growth of erythropoietic cells and stimulation of erythropoietic cell proliferation, and analysis performed thereafter requires isolation of the erythropoietic cells using magnetic cell separation. It is also noted that in the culture systems taught by Crouch, the hematopoietic progenitor cells are isolated or purified from other cells using Ficoll-Hypaque density gradient centrifugation to remove any other components including erythrocytes which are hemoglobin-containing cells, before subjecting the cells to luciferase-based ATP bioluminescence assay. Applicant in Example 1 appears to provide the same method as that taught by Crouch, in obtaining the cell population comprising primitive hematopoietic cells substantially free of hemoglobin, prior to performing the claimed assay. Accordingly, Applicant's contention that there is inclusion of hemoglobin in the teaching of Bell which renders it non-combinable with the luciferase-based ATP luminescence assay of Crouch because of the impairing effect of the heme moiety in luminescence systems, is misguided because both systems individually and selectively require removal of contaminating components, such as heme moieties, prior to subjecting the cells to further analysis. Additionally, the

components set forth in the combined references are consonant with the elements relied upon for support in Applicant's disclosure. Accordingly, the hemoglobin components in the teaching of Bell would have been removed by the Ficoll-Hypaque density gradient centrifugation in the method of Crouch.

B) Dr. Rich performed experiments to show that if whole blood is present in luciferase-based ATP bioluminescence assays, false positive results are obtained, thereby rendering the assays unable to correlate luminescence values to the proliferative status of the primitive hematopoietic cell populations. Applicant specifically states that Bell et al. teach use of hemoglobin in enhancing proliferation of cells culture system; hence, it is not combinable in any shape or form with the luciferase-based ATP system of Crouch et al. since inclusion of hemoglobin molecules causes significant impairment of the luminescence generated by ATP luciferase in ATP bioluminescence assays.

In response to Applicant's argument that the references cited are not combinable because of the use of hemoglobin by Bell in his culture system which is incompatible with luciferase-based ATP detection systems due to interference from absorption of light by the heme moiety in luminescence systems, it is noted that methods taught by Bell incorporate hemoglobin in the culturing systems only to promote growth of erythropoietic cells and stimulation of erythropoietic cell proliferation, and analysis performed thereafter requires isolation of the erythropoietic cells using magnetic cell separation. It is also noted that in the culture systems taught by Crouch, the hematopoietic progenitor cells are isolated or purified from other cells using Ficoll-

Hypaque density gradient centrifugation to remove any other components including erythrocytes which are hemoglobin-containing cells, before subjecting the cells to luciferase-based ATP bioluminescence assay. Applicant in Example 1 appears to provide the same method to obtain the cell population comprising primitive hematopoietic cells substantially free of hemoglobin. Accordingly, Applicant's contention that there is inclusion of hemoglobin in the teaching of Bell which renders it non-combinable with the luciferase-based ATP luminescence assay of Crouch because of the impairing effect of the heme moiety in luminescence systems, is misguided because both systems individually and selectively require removal of contaminating components, such as heme moieties, prior to subjecting the cells to further analysis. Additionally, the components set forth in the combined references are consonant with the elements relied upon for support in Applicant's disclosure. Accordingly, the hemoglobin components in the teaching of Bell would have been removed by Ficoll-Hypaque density gradient centrifugation in the method of Crouch.

9. For reasons aforementioned, no claims are allowed.

10. Applicant's submission of the requirements for the joint research agreement prior art exclusion under 35 U.S.C. 103(c) on May 8, 2005 prompted the new grounds of rejection under 37 CFR 1.109(b) presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.02(l)(3). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gailene R. Gabel
Patent Examiner
Art Unit 1641
July 20, 2005

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
07/25/05